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QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
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Appl. No.	:	10/620,315	Confirmation No. 7949
Applicant	:	Moshe Rosenberg, et al.	
Filed	:	July 14, 2003	
TC/A.U.	:	1615	
Examiner	:	Melissa S. Mercier	
Docket No.	:	309J-000310US	
Customer No.	:	22798	

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APPEAL BRIEF

REAL PARTY IN INTEREST

The real part of interest in the present appeal is The Regents of the University of California, the assignee of the above-referenced application.

RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' Attorney, and the assignee of the above-referenced application are unaware of any appeals or interferences that will directly affect, be directly affected by, or have a bearing on, the Board's decision in the present appeal.

STATUS OF CLAIMS

On September 2, 2009, Appellants appealed from the final rejection of claims 1 to 15, 20 to 23, 25, 26 and 67. The present application was filed on July 14, 2003 with 66 original claims. In response to the Restriction Action of June 28, 2006, Applicants elected Group I claims 1 to 26 to composite gels. Claim 16 was cancelled in Applicants' Response

of May 24, 2007. Claims 17 to 19 and 24 were cancelled in Applicants' Response of May 8, 2008. New claim 67 was added in Applicants' Response of April 8, 2009. Accordingly, Appellants believe that claims 1 to 15, 20 to 23, 25, 26 and 67 are under consideration.

STATEMENT OF AMENDMENTS

The claims were not amended in response to the final Office Action mailed July 14, 2009. Accordingly, the appealed claims are the claims as provided in the Amendment dated April 8, 2009, as filed in Response to the Office Action dated March 13, 2009.

SUMMARY OF CLAIMED SUBJECT MATTER

Appellants' invention provides composite gels comprising, e.g., dispersed phase lipid droplets or particles dispersed in a continuous phase aqueous matrix of cross-linked proteins. The dispersed phase comprises 20% or less of free fatty acids. The continuous phase has a pH ranging from pH 4 to pH 9 and is not cross-linked with divalent linkers or aldehydes. The composite gel of the claims includes supplemental materials, which are protected by the continuous phase matrix against degradation, modification or removal from the gel during passage through the rumen of a ruminant animal. Support for the claims can be found throughout the specification, e.g., in the Examples section starting at paragraph 100. Specifically, support for the dispersed phase dispersed droplets and particles can be found, e.g., at paragraphs 44 and 59; and the Filler Composition section starting at paragraph 77. Support for 20% or less of free fatty acids can be found, e.g., paragraphs 77 and 78; and paragraphs 22, 44, 48, 65, 80 and 81. Specific support for the continuous phase aspects can be found, e.g., in the section entitled The Matrix Suspension, starting at paragraph 67, and in paragraphs 22, 45, and 86. Specific support for supplemental constituents can be found, e.g., at paragraphs 13, 21, 48, 65, 73 and 75.

The appealed claims are set forth in Appendix A.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

In the final Office Action dated July 14, 2009, claims 1 to 15, 20 to 26 and 67 were rejected under 35 U.S. Code 112, first paragraph as allegedly failing to comply with the

written description requirement; and, claims 1 to 4, 8, 13, 14, 21 to 23, 25 and 26 were rejected under 35 U.S. Code 102(b) based on alleged anticipation of the claimed composite gels by "A Hard Boiled Egg".

ARGUMENT

Rejection of claims 1 to 15, 20 to 26 and 67 under 35 U.S.C. §112, 2nd paragraph.

Claims 1 to 15, 20 to 26 and 67 were rejected under 35 U.S.C. §112, second paragraph for alleged failure to comply with the written description requirement. These claims stand or fall together.

The term "composite gel", as used herein, refers to a continuous phase matrix of cross-linked proteins forming an aqueous gel surrounding a dispersed phase of lipid droplets or particles. See, e.g., paragraph 47 of the original specification. The composite gel is typically prepared by forming an emulsion of lipid droplets ("filler composition") in an aqueous protein solution. The lipid droplets can include fatty acids. On cross-linking of the proteins, the filler composition droplets become the dispersed phase droplets in the composite gel matrix.

The final Office Action of July 14, 2009 (the Office Action) at page 5 alleges that dispersed phase droplets or particles "comprising 20% or less of free fatty acids" is new subject matter, not supported by the original specification. However, free fatty acids and proportions of fatty acids are well supported in the specification.

Applicants used the terms "fatty acid" and "free fatty acid" interchangeably in the original specification. The original specification states that 0 to 20% of the dispersed phase can be fatty acids. This is not disputed in the rejection. The rejection is apparently based on the argument that a "fatty acid" should not be considered a "free fatty acid". However, this is a distinction without a difference. The structure of a fatty acid is the same as the structure of a free fatty acid. Historically, when fatty acids were first described, they were found to be freed from triglycerides (e.g., oils and fats) by hydrolysis. For example, L. G. Wade, Jr., Organic Chemistry, 5th Edition, Pearson Education, Inc., (2003), at page 900, describes fatty acids as "long-chain aliphatic acids derived from the hydrolysis of fats and oils." However, whether a fatty acid was "freed" from a triglyceride or was synthesized

some other way, it is still a fatty acid. Those of skill in the art, and the present specification, sometimes drop the "free" and simply discuss "fatty acids".

Dispersed phase droplets or particles comprising 20% or less "free fatty acids" (aka, "fatty acids") in are described throughout the original specification. As the Examiner stated at page 5 of the Office Action:

> "[T]he specification discloses supplemental components [i.e., constituents] can be present in the amount of 0-75%, preferably 1-20%, and the supplementary components [constituents] can include fatty acids ..." See paragraph 78 of the specification.

These supplemental constituents are described in the context of the filler composition, e.g., which forms emulsion droplets that become the dispersed phase lipid droplets on cross-linking of the continuous phase matrix. Because the Office agrees the original specification discloses dispersed phase fatty acids in the range cited in the claim, and because fatty acids are free fatty acids, adequate written description is provided for one of skill in the art to believe the Applicant was in possession of the claimed subject matter at the time of filing the application.

Applicants note the word "free" could have been deleted from the rejected claim 1 after the issue arose in the final rejection. However, because the issue is immaterial, Applicants elected to retain the word "free" to avoid further delay (e.g., an RCE) in addressing the obviousness rejection in this Appeal. Such an amendment would have been immaterial because, the alternate terms are equivalent, and because the claims are not anticipated even without the presence of the "20% or less free fatty acids" limitation in the claims.

Applicants respectfully request the Board of Appeals find the written description of 20% or less free fatty acids to be adequate. Optionally, Applicants request instruction to allow amendment deleting the term "free" from claim 1 in order to render the written description issue moot, even based on the rationale of the Office Action.

Rejection of claims 1 to 4, 8, 13, 14, 21 to 23, 25 and 26 under 35 U.S.C. §102(b).

Claims 1 to 4, 8, 13, 14, 21 to 23, 25 and 26 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by "A Hard Boiled Egg". These claims stand or fall together.

Applicants have previously noted, e.g., in the Response of April 8, 2009 (the Response), that multiple limitations of the claims not explicitly or inherently present in a hard boiled egg. For example, the hard boiled egg does not include a dispersed phase of lipid droplets, droplets dispersed in a continuous phase matrix, or supplemental constituents in a composite gel protected against degradation in a rumen. Moreover, the Office Action does not even allege all limitations of the claims, so no case has been stated on the record for the rejections.

The allegations forming the basis of the rejection are often conclusory, fail to acknowledge limitations of the claims, and/or ignore facts on the record. For example, at page 3 of the Office Action, "[t]he egg white [is alleged to] constitute the continuous phase ..." At page 4 of the Office Action, it is alleged "[t]he yolk of the egg meets the limitations of Applicants dispersed phase." Finally, at page 4, the Examiner states "it is the position of the examiner; absent a showing of evidence to the contrary that [the hard boiled egg] would not provide the same functional properties", e.g., protection against degradation in a rumen. That is, the rejection identifies the yolk as the dispersed phase, and the white as the continuous phase; with the further allegation essentially that constituents of hard boiled eggs would not be degraded if eaten by a cow. However, the allegations are not backed up with facts reasonably supporting the statements.

Applicants have previously noted (e.g., the Responses of April 8, 2009, and November 20, 2009) that "the rejection fails to allege, e.g., a dispersed phase [dispersed within a continuous phase matrix] wherein the lipid droplets are protected against degradation in passage through a rumen." Emphasis added.

In the Definitions section, at paragraph 44 of in the present specification, the "term 'dispersed phase' ... refers to a dispersion of lipid droplets or particles protected within the continuous phase protein gel matrix of a composite gel." At paragraph 45 the "term 'continuous phase' ... refers to the cross-linked protein gel matrix surrounding dispersed phase droplets or particles in a composite gel of the invention."

The rejection states that the hard boiled egg "yolk would constitute ... lipid droplets or particles within a dispersed phase." Applicants note that this has nothing to do with the present claims. For example, the lipid droplets are the dispersed phase, so should not properly be considered within the dispersed phase (unless something can be considered within itself). Moreover, the claims require the droplets to be dispersed within the gel matrix, not within the recited dispersed phase. In addition, one can plainly see that the yolk is neither "droplets" nor "dispersed". Accepting for argument that the egg white represents the Examiner's continuous phase, we see that nothing is "dispersed within the continuous phase matrix", as required by the claim, nor is this alleged in the Office Action. The allegations do not support the rejections, and the actual facts do not support the rejections.

Claim 1 requires that "the dispersed phase droplets ... are dispersed and embedded within the continuous phase matrix". First, the offered yolk is singular and therefore can not represent the plural droplets. Second, the yolk is embedded in the white, but not dispersed within the white matrix. Webster's - "disperse": to spread or distribute from a fixed or constant source; "dispersion": to distribute (as fine particles) more or less evenly throughout a medium. Because, the yolk is not droplets, and is not dispersed in the matrix, it can not represent the dispersed phase of a composite gel, as described in the original specification. The identified components of a hard boiled egg do not correspond structurally or functionally to the elements of the claimed composite gel.

The Office Action has suggested that constituents of a hard boiled egg are "inherently" protected against degradation in a rumen, and that Applicants have never shown evidence to the contrary. As a preliminary matter, because the hard boiled egg is neither structurally or functionally the same as the claimed composite gels, Applicants have no burden to show any evidence of whether the different hard boiled egg would be degraded in a rumen. Yet, in previous Responses, Applicants have actually repeatedly provided such evidence. For example, in the Response at page 7, Applicants noted:

> "Applicants have previously stated that the Office's own reference acknowledges that such eggs are 'digested easily, even by [human] infants'. Yet the Action [of March 13, 2009] at page 4 continues to suggest that '[s]ince a hard boiled egg meets the structural limitations of the instant claims, it is the position of the examiner; absent a showing of

> evidence to the contrary that it would not provide the same properties.' Applicants have previously provided such evidence that is apparently discarded without comment by the Office. Further, the entire rationale for rejection is moot since, as discussed above, the structures are in fact not the same."

It is common knowledge to one of skill in the art that the constituents of a hard boiled egg are not protected against degradation in a rumen (which, can actually even digest grass). Further, the present specification, e.g., at paragraph 81 suggests that the "physical character of the final composite gel, and the extent to which gel constituents are protected against digestion, modification, or biohydrogenation in the rumen, can be significantly influenced by the particle size distribution of the filler phase." Due to the lack of dispersion of lipids as droplets in the egg white matrix, rumen protection would have been expected to fail, according to the specification. Applicants have previously provided additional evidence (in the Responses of April 18, 2009 and November 20, 2008) that a hard boiled egg would not be rumen protective. Applicants have noted that the "Structure of the Egg", (http://www.urbanext.uius.edu/eggs/res16-egg.html; unknown publication date) sited in the Office Action of October 28, 2008, confirms that yolk "is digested easily, even by infants." Therefore, although Applicants were not required to provide the evidence suggested, multiple examples of such evidence has been previously provided.

Hard boiled eggs are not composite gels of the claims and do not have the characteristics of the composite gels of the invention (shown to function in multiple examples of the specification). Applicants respectfully request the rejections for alleged anticipation by hard boiled eggs be withdrawn and the claims allowed.

CONCLUSION

Appellants submit that the Examiner's rejection of claims 1 to 15, 20 to 23, 25, 26 and 67 is improper. Withdrawal of the rejections by the Examiner or reversal of this rejection by the Board is respectfully requested.

The Commissioner is authorized to charge the fee under 37 C.F.R. §1.17(c) and any other required fees, or to credit any overpayments, to Deposit Account 50-0893.

If a telephone conference would expedite prosecution of the above-identified application, the Examiner is invited to phone the undersigned at (510) 769-3510.

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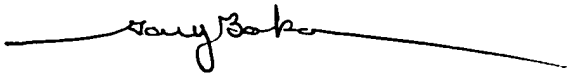
Respectfully submitted,



Gary Baker
Reg. No: 41,595

Attachments:

1) Appendix A - Appealed Claims for 11/045,864;
2) Appendix B - Structure of the Egg: http://www.urbanext.uius.edu/eggs/res16-egg.html
3) Appendix C - Related Proceedings
4) A fee transmittal sheet; and,
5) A receipt indication postcard.

APPENDIX A

APPEALED CLAIMS FOR 11/045,864

1. (Previously presented) A composite gel comprising:

a) a dispersed phase comprising lipid droplets or particles comprising 20% or less of free fatty acids;

b) a continuous phase aqueous matrix comprising a pH ranging from about pH 4 to pH 9, and one or more cross-linked proteins not cross-linked with a divalent linker, formaldehyde, glutaraldehyde or other aldehydes; and,

c) supplemental constituents;

wherein the dispersed phase droplets or particles are dispersed and embedded within the continuous phase matrix; and, whereby supplemental constituents or lipid droplets, suitable for ruminant ingestion, are protected against degradation, modification, or removal from the gel during passage through a rumen.

2. (Original) The composite gel of claim **1**, wherein the supplemental constituents are selected from the group consisting of vitamins, nutrients, proteins, amino acids, polyunsaturated lipids, minerals, bioactive materials, and pharmaceuticals.

3. (Original) The composite gel of claim **1**, wherein the supplemental constituents are in the dispersed phase.

4. (Original) The composite gel of claim **1**, wherein the supplemental constituents are in the continuous phase matrix.

5. (Original) The composite gel of claim **1**, wherein the lipid droplets range in size from about 0.1 μm to about 50 μm.

6. (Original) The composite gel of claim **5**, wherein the lipid droplets range in size from about 0.1 μm to about 1 μm.

7. (Previously presented) The composite gel of claim **5**, wherein the lipid droplets comprise a specific surface area of more than about 10 m^2/ml of a filler phase surface in the composite gel.

8. (Original) The composite gel of claim **1**, wherein the lipid droplets comprise one or more oils, fats, monoglycerides, diglycerides, triglycerides, or free fatty acids.

9. (Original) The composite gel of claim **1**, wherein the lipid comprises about 10% to about 50%, or more, conjugated linoleic acid.

10. (Original) The composite gel of claim **9**, wherein the lipid comprises about 25%, or more, conjugated linoleic acid.

11. (Previously presented) The composite gel of claim **1**, wherein the dispersed phase lipid comprises oil selected from the group consisting of: corn oil, poppy seed oil, fish oil, cotton seed oil, soybean oil, walnut oil, safflower oil, sunflower oil, sesame oil, canola oil, and linseed oil.

12. (Original) The composite gel of claim **1**, wherein the lipid comprises fatty acids selected from the group consisting of oleic acid, conjugated linoleic acid, linolenic acid, phytanic acid, omega 3 fatty acids, docosahexaenoic acid, and eicosapentaenoic acid.

13. (Original) The composite gel of claim **1**, further comprising one or more emulsifiers.

14. (Original) The composite gel of claim **1**, further comprising one or more hydrocolloids.

15. (Original) The composite gel of claim **1**, wherein the proteins are selected from the group consisting of whey proteins, bovine blood plasma proteins, gelatin, peanut proteins, cereal proteins, fish proteins, soy proteins, and porcine blood proteins.

16 to 19 (Cancelled)

20. (Original) The composite gel of claim **1**, wherein the proteins are cross-linked by heat induced formation of disulfide bonds between the proteins.

21. (Original) The composite gel of claim **1**, wherein the proteins are predominantly cross-linked by disulfide bonds, hydrophobic interactions, ionic interactions, or hydrogen bonding.

22. (Original) The composite gel of claim **1**, wherein the continuous phase comprises about 10% to about 50% total solids by weight.

23. The composite gel of claim **22**, wherein the total solids comprise about 10% to about 100% protein by weight.

24. (Cancelled)

25. (Original) The composite gel of claim **1**, wherein the continuous phase comprises about 10% to about 95% water.

26. (Original) The composite gel of claim **1**, wherein the continuous phase comprises calcium, magnesium, sodium, or phosphate.

Claims 27 to 66 (Cancelled)

Claim 67. (Previously presented) The composite gel of claim **1**, wherein said cross-linking is heat cross linking at a temperature of 80°C to 120°C.

APPENDIX B

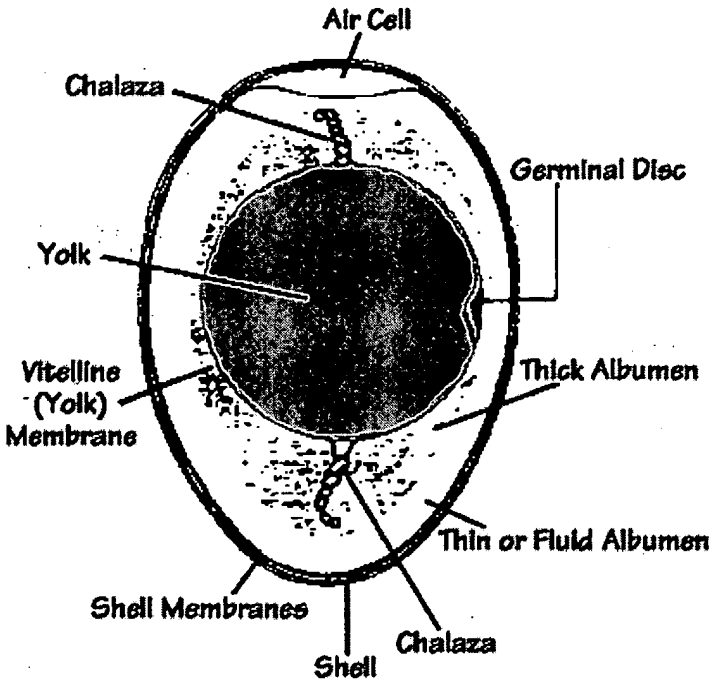
EVIDENCE APPENDIX

Structure of the Egg: http://www.urbanext.uius.edu/eggs/res16-egg.html; cited by Examiner.

Incubation and Embryology - University of Illinois

Structure of the Egg

The egg is a biological structure intended by nature for reproduction. It protects and provides a complete diet for the developing embryo, and serves as the principal source of food for the first few days of the chick's life. The egg is also one of the most nutritious and versatile of human foods.



When the egg is freshly laid, the shell is completely filled. The air cell is formed by contraction of the contents during cooling and by the loss of moisture. A high-quality egg has only a small air cell.

The yolk is well-centered in the albumen and is surrounded by the vitelline membrane, which is colorless. The germinal disc, where fertilization takes place, is attached to the yolk. On opposite sides of the yolk are two, twisted, whitish cord-like objects known as chalazae. Their function is to support the yolk in the center of the albumen. Chalazae may vary in size and density, but do not affect either cooking performance or nutritional value.

A large portion of the albumen is thick. Surrounding the albumen are two shell membranes and the shell itself. The shell contains several thousand pores that permit the egg to "breathe."

Composition

An average-sized egg weighs approximately 57 grams (about 2 ounces). Of this weight, the shell constitutes 11 percent; the white, 58 percent; and the yolk, 31 percent. Normally, these proportions do not vary appreciably for small or large eggs. The percentage composition of the edible portions is:

Percent	Water	Protein	Fat	Ash

Whole egg	74	13	11	1
White	88	11	..	..
Yolk	48	17	33	1

Essential nutrients

Eggs are especially valuable as a source of protein. In fact, egg protein is used as the standard against which the quality of other food proteins is measured. One egg contains about 6 to 7 grams of protein. People of all ages need adequate protein for building and repairing body tissues.

The fat in the yolk is so finely emulsified that it is digested easily, even by infants. The ratio of unsaturated to saturated fats is about 2 to 1. This is considered very desirable. Oleic acid is the main unsaturated fat. It has no effect on blood cholesterol. Eggs contain vitamin A, the B vitamins (thiamin, riboflavin, and niacin), and vitamin D. All are necessary during childhood and adolescence for growth. Eggs also contain an abundant supply of minerals, such as iron and phosphorus, that are essential for building and maintaining strong, healthy bodies. But eggs are low in calcium (it is in the shell), and contain little or no vitamin C.

Individuals on weight-reducing programs find eggs beneficial. To lose weight, calorie intake must be reduced, while maintaining a well-balanced diet. An egg provides good nutrition and contains only about 80 calories.

Value of eggs

Food prices continue to climb, particularly for high-protein foods, and consumers are constantly searching for ways to reduce their food bill. One way is to include more eggs in the diet. Comparing protein foods on a pound-for-pound basis, eggs cost about 95 cents a pound when large eggs are selling for 64 cents a dozen. It is difficult to purchase any other high-protein food--meat or fish--for this low price.

Source: H.S. Johnson and S. F. Ridlen

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APPENDIX C

RELATED PROCEEDINGS

(none)